

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

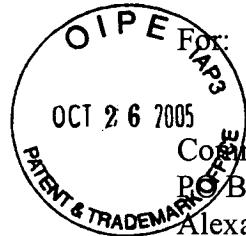
In re the Application of: **Stamm et al**

Application No. **09/899,026**

Group Art Unit: **1615**

Filed: **July 6, 2001**

Examiner: **H. Sheikh**



For: **Fenofibrate Pharmaceutical Composition Having High Bioavailability and Method for Preparing It**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Information Disclosure Statement

Pursuant to 37 CFR §§ 1.56, 1.97 and 1.98, Applicants bring to the attention of the Examiner the documents listed on the attached PTO-1449 Form. For the Examiner's convenience, the references cited on the PTO-1449 Form have been numbered and tabbed for easy access to and identification of the documents.

With respect to the documents listed on the PTO-1440 Form, the Examiner's attention is particularly directed to the following:

| PTO-1449 Form Cite No. | Document |
|------------------------------|---|
| 1 | The dissolution profile on page 12 at Table VII in Laboratoires Fournier's document entitled "Fenofibrate Tablets 54-160 MG Dissolution Test Conditions Development Studies, Dissolution Test Specification Recommendations." |
| 2 | The charge of inequitable conduct and/or fraud on the PTO in the prosecution of the application leading to US Patent No. 6,652,881 to which the present application claims priority, and the charge of unenforceability of US Patent Nos. 6,074,670, 6,277,405 and 6,589,552 to which the present application claims priority at, for example, ¶¶ 19-86 at pages 4-14; at ¶¶ 105-181 at pages 47-62 in the Second Amended Answer, Affirmative Defenses, and Counterclaims filed by Teva Pharmaceuticals USA, Inc. on July 29, 2005, in <i>Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc.</i> , US District Court for the District of Delaware, CA No. 02-1512. |
| 3 | The charge of inequitable conduct and/or fraud on the PTO in the prosecution of the application leading to US Patent No. 6,652,881, to which the present application claims priority at, for example, ¶¶ 73-107 at pages 18-24 in the First Amended Counterclaims filed by Impax Laboratories, Inc. on September 23, 2005, in <i>Abbott Laboratories et al v. Impax Laboratories, Inc.</i> , US District Court for the District of Delaware, CA No. 03- |

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| | 120. |
| 4 | The charge of inequitable conduct and/or fraud on the PTO in the prosecution of the application leading to US Patent No. 6,652,881, to which the present application claims priority at, for example, ¶¶ 85-102 at pages 29-32 in the Amended Complaint filed by CVS Pharmacy, Inc. et al on September 23, 2005, in <i>In re TriCor Direct Purchaser Antitrust Litigation</i> , US District Court for the District of Delaware, Case No. 05-340. |
| 5 | The charge of inequitable conduct and/or fraud on the PTO in the prosecution of the application leading to US Patent No. 6,652,881, to which the present application claims priority at, for example, ¶¶ 92-109 at pages 31-34 in the Amended Complaint filed by Walgreen Co. et al on September 23, 2005, in <i>In re TriCor Direct Purchaser Antitrust Litigation</i> , US District Court for the District of Delaware, Case No. 05-340. |
| 6 | The charge of inequitable conduct and/or fraud on the PTO in the prosecution of the application leading to US Patent No. 6,652,881 to which the present application claims priority, and the charge of unenforceability of US Patent Nos. 6,074,670, 6,277,405 and 6,589,552 to which the present application claims priority at, for example, ¶¶ 81-85 at pages 26-28 in the Complaint filed by Painters' District Council No. 30 Health and Welfare Fund et al on September 23, 2005, in <i>In re TriCor Direct Purchaser Antitrust Litigation</i> , US District Court for the District of Delaware, Case No. 05-340. |
| 7 | The charge of inequitable conduct and/or fraud on the PTO in the prosecution of the application leading to US Patent No. 6,652,881, to which the present application claims priority at, for example, ¶¶ 129-146 at pages 50-54 in the First Amended Complaint filed by Louisiana Wholesale Drug Company, Inc. et al on October 3, 2005, in <i>In re TriCor Direct Purchaser Antitrust Litigation</i> , US District Court for the District of Delaware, Case No. 05-340. |
| 8 | The charge of invalidity under § 103 of US Patent No. 6,074,670 on page 4; the charge of indefiniteness under § 112, second paragraph, of US Patent No. 6,277,405 on page 5; the charge of lack of enablement under § 112, first paragraph of US Patent Nos. 6,074,670, and 6,277,405 on page 6; and the charge of unenforceability of US Patent Nos. 6,074,670, and 6,277,405 on page 7 in Defendant's Responses to Plaintiffs ... Interrogatories... filed by Impax Laboratories, Inc. on August 6, 2003, in <i>Abbott Laboratories et al v. Impax Laboratories, Inc.</i> , US District Court for the District of Delaware, CA No. 03-120. |
| 9 | The charge of inequitable conduct and/or fraud on the PTO in the prosecution of the application leading to US Patent No. 6,652,881, to which the present application claims priority at, for example, ¶¶ 15-69 at pages 7-14 in the Amended Answer filed by Impax Laboratories, Inc. on January 4, 2005, in <i>Abbott Laboratories et al v. Impax Laboratories, Inc.</i> in the United States District Court for the District of Delaware, CA No. 03-120. |

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| 10 | The charge of lack of enablement under § 112, first paragraph, of US Patent Nos. 6,277,405, and 6,652,881 at pages 2-5 of Reply Memorandum in Support of Defendant Impax Laboratories, Inc.'s Motion ... for Partial Summary Judgment of Invalidity for Nonenablement filed by Impax Laboratories, Inc. on February 25, 2005, in <i>Abbott Laboratories et al v. Impax Laboratories, Inc.</i> in the United States District Court for the District of Delaware, CA No. 03-120. |
| 11 | Memorandum Opinion by District Judge Jordan dated May 6, 2005, in <i>Abbott Laboratories et al v. Impax Laboratories, Inc.</i> , in the United States District Court for the District of Delaware, CA No. 03-120, <u>denying</u> Impax Laboratories Motion ... for Partial Summary Judgment of Invalidity for Nonenablement of US Patent Nos. 6,277,405, and 6,652,881 (see pages 15-19). |
| 12 | The charge of inequitable conduct and unenforceability of US Patent Nos. 6,074,670, 6,277,405, 6,589,552, and 6,652,881, under § 102(f) on the grounds that the inventors knowingly omitted other inventors asserted by Teva Pharmaceuticals USA in Defendant Teva Pharmaceuticals USA, Inc.'s Opening Brief in Support of Its Motion for Summary Judgment that the Stamm Patents are Unenforceable Because the Named Inventors Filed False Declarations filed on December 23, 2004, in <i>Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc.</i> , The United States District Court for the District of Delaware, Civil Action No. 02-1512. |
| 13 | The charge of invalidity under § 112, first paragraph, for failing to set forth the best mode asserted by Teva Pharmaceuticals USA in Defendant Teva Pharmaceuticals USA, Inc.'s Opening Brief in Support of Its Motion for Summary Judgment that the Stamm Patents are Invalid under 35 USC § 112 For Failure to Set Forth the Best Mode of the Inventors for Carrying Out the Invention filed on December 10, 2004, in <i>Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc.</i> , The United States District Court for the District of Delaware, Civil Action No. 02-1512. |
| 14 | Memorandum Opinion by District Judge Jordan dated May 6, 2005, in <i>Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc.</i> , in the United States District Court for the District of Delaware, CA No. 02-1512, <u>denying</u> Teva Pharmaceuticals USA, Inc.'s Motions for Summary Judgment that the Stamm patents are unenforceable under § 102(f) on the grounds that the inventors knowingly omitted other inventors (see pages 8-10); that the patents are invalid under § 112, second paragraph (see page 11); and that the Stamm patents are invalid under § 112, first paragraph, for failing to set forth the best mode (see pages 15-18). |
| 23 | Letter from Teva/Novopharm to Fournier Pharma Inc. charging Invalidity and Ambiguity of claims in Canadian Patent Nos. 2,219,475 and 2,372,576 assigned to Laboratoires Fournier, SA (pages 1-15) (September 19, 2005). |

Applicants bring to the Examiner's attention the following litigations:

- (i) *In re TriCor Indirect Purchaser Antitrust Litigation*, District of Delaware, Civil Action No. 05-360;
- (ii) *CVS Pharmacy, Inc. et al v. Abbott Laboratories, Fournier Industrie et Santé, and Laboratoires Fournier SA*, District of Delaware, 1:05-cv-00605-KAJ;
- (iii) *Walgreen Co. et al v. Abbott Laboratories, Fournier Industrie et Santé, and Laboratoires Fournier SA*, District of Delaware, 1:05-cv-00404-KAJ;
- (iv) *Pacificare Health Systems, Inc. v. Abbott Laboratories, Fournier Industrie et Santé, and Laboratoires Fournier SA*, District of Delaware, 1:05-cv-00591-KAJ;
- (v) *Painters District Council No. 30 Health and Welfare Fund et al v. Abbott Laboratories, Fournier Industrie et Santé, and Laboratoires Fournier SA*, District of Delaware, 1:05-cv-00360-KAJ;
- (vi) *Louisiana Wholesale Drug Company, Inc. v. Abbott Laboratories, Fournier Industrie et Santé, and Laboratoires Fournier SA*, District of Delaware, 1:05-cv-00340-KAJ;
- (vii) *Paul T. Tegan v. Abbott Laboratories, Fournier Industrie et Santé, and Laboratoires Fournier SA*, Central District of California, 2:05-cv-05410-GAF-AJW.

Applicants bring to the Examiner's attention the following Oppositions:

| PTO-1449 Form Cite No. | Document |
|---------------------------|---|
| 15 | Opposition to European Patent No. 1 273 293 |
| 16 | Opposition to Israel Patent No. 130790 |

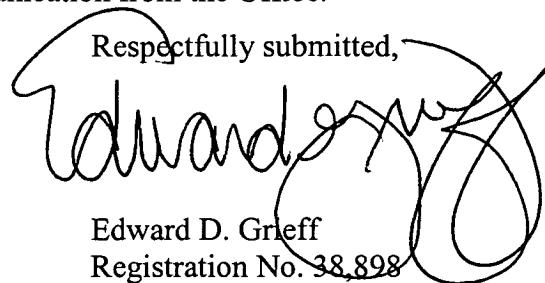
The submission of this Information Disclosure Statement does not represent that a search has been made and does not constitute an admission that the listed documents, oppositions and/or litigations are material to patentability or that the listed documents, oppositions and/or litigations are prior art.

No fees are believed to be due; however, the Commissioner is authorized to charge any necessary fees or credit any overpayments to Deposit Account No. 22-0261.

October 26, 2005

Applicants respectfully request that the Examiner initial and return a copy of the enclosed PTO-1449 Form with the next communication from the Office.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Edward D. Grieff". The signature is fluid and cursive, with "Edward" on the left and "D. Grieff" on the right, with a stylized flourish at the end.

Edward D. Grieff
Registration No. 38,898

Date: October 26, 2005

Venable LLP
575 7th Street, NW
Washington, DC 20004
Phone: 202-344-4382

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Complete if Known**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheikh

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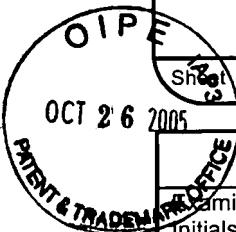
of

4

Attorney Docket Number

224407

OCT 26 2005

**NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|--------------------|-----------------------|---|----------------|
| | 1 | Laboratoires Fournier S.A. document entitled "Fenofibrate Tablets 54-160 mg Dissolution Test Conditions Development Studies, Dissolution Test Specification Recommendations" | |
| | 2 | "Second Amended Answer, Affirmative Defenses, and Counterclaims" filed by Teva on 7-29-2005 in Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc., DE, CA No. 02-1512. | |
| | 3 | "First Amended Counterclaims" filed by Impax on 9-23-2005 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ. | |
| | 4 | "Amended Complaint" filed by CVS Pharmacy et al on 9-23-2005 in In Re TriCor Direct Purchaser Antitrust Litigation, Delaware, CA No. 05-340. | |
| | 5 | "Amended Complaint" filed by Walgreen Co. et al on 9-23-2005 in In Re TriCor Direct Purchaser Antitrust Litigation, Delaware, CA No. 05-340. | |
| | 6 | "Complaint" filed by Painters' District Council No. 30 et al on 9-23-2005 in In Re TriCor Direct Purchaser Antitrust Litigation, Delaware, CA No. 05-340. | |
| | 7 | "First Amended Complaint" filed by Louisiana Wholesale Drug Co. et al, on 10-3-2005 in In Re TriCor Direct Purchaser Antitrust Litigation, Delaware, CA No. 05-340. | |
| | 8 | "Defendant's Responses to Plaintiffs Interrogatories" filed by Impax on 8-6-2003 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ. | |
| | 9 | "Amended Answer" filed by Impax on 1-4-2005 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ. | |
| | 10 | "Reply Memorandum" filed by Impax on 2-25-2005 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ. | |

| Examiner Signature | Date Considered |
|--------------------|-----------------|
| | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

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of

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| | |
|----------------------|--------------|
| Application Number | 09/899,026 |
| Filing Date | July 6, 2001 |
| First Named Inventor | Stamm |
| Art Unit | 1615 |
| Examiner Name | Sheikh |

Attorney Docket Number 224407

OCT 26 2005

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|--------------------|-----------------------|---|----------------|
| | 11 | "Memorandum Opinion" by District Judge Jordan dated 5-6-2005 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ. | |
| | 12 | "Opening Brief in Support of Motion for Summary Judgment" by Teva filed on 12-23-2004 in Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc., Delaware, CA No. 02-1512. | |
| | 13 | "Opening Brief in Support of Motion for Summary Judgment" by Teva filed on 12-10-2004 in Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc., Delaware, CA No. 02-1512. | |
| | 14 | "Memorandum Opinion" by District Judge Jordan dated 5-6-2005 in Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc., Delaware, CA No. 02-1512. | |
| | 15 | Opposition to European Patent No. 1 273 293 filed on 9-2-2005 by Ethypharm (French Language Document). | |
| | 16 | Opposition to Israel Patent No. 130790 filed 5-4-2005 by Teva; and Remarks in Response to Opposition filed on 9-23-2005. (English Language Translations). | ✓ |
| | 17 | Munoz et al, Atherosclerosis, 110(Suppl.):S45-S48 (1994). | |
| | 18 | Pharmaceutical Pelletization Technology, Marcel Dekker, Inc., Volume 37, pages 1-13; 160-161; and 234-235 (1989). | |
| | 19 | Modern Pharmaceutics, Third Edition, Marcel Dekker, Inc., pages 131-133 and 335-336 (1996). | |
| | 20 | Pharmaceutical Dosage Forms, Tablets, Second Edition, Marcel Dekker, Inc., pages 5-28; 88-107; 133; 142; 160-165; and 260-267 (1989). | |

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|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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|------------------------------|---|----|---|--------------------------|--------------|
| Substitute for form 1449/PTO | | | | Complete if Known | |
| | | | | Application Number | 09/899,026 |
| | | | | Filing Date | July 6, 2001 |
| | | | | First Named Inventor | Stamm |
| | | | | Art Unit | 1615 |
| | | | | Examiner Name | Sheikh |
| Sheet | 3 | of | 4 | Attorney Docket Number | 224407 |

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|---|-----------------------|---|----------------|
| OCT 26 2005 P E PATENT & TRADEMARK OFFICE IAPS | 21 | Shepherd, Atherosclerosis, 110(Suppl.):S55-S63 (1994). | |
| | 22 | Adkins et al, Drugs, 54(4):615-633 (October 1997). | |
| | 23 | Letter from Teva/Novopharm to Fournier Pharma Inc. regarding Invalidity and Ambiguity of Canadian Patent Nos. 2,219,475 and 2,372,576 (pages 1-15) (September 19, 2005). | |
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| Examiner Signature | Date Considered |
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 4 of 4

Complete if Known

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| Application Number | 09/899,026 |
| Filing Date | July 6, 2001 |
| First Named Inventor | Stamm |
| Art Unit | 1615 |
| Examiner Name | Sheikh |
| Attorney/Agent Number | 224407 |

U. S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

| FOREIGN PATENT DOCUMENTS | | | | | |
|--------------------------|-----------------------|---|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear |
| | | Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | | | |
| | 28 | CA 2,142,848 | 03-17-1994 | Janssen Pharmaceutica | |
| | 29 | CA 960,670 | 01-07-1975 | Orchimed SA | |
| | 30 | WO 98/31360 | 07-23-1998 | Pharma Pass | |
| | 31 | WO 97/12581 | 04-10-1997 | Pharma Pass | |
| | 32 | CA 2,219,475 | 07-09-2002 | Laboratoires Fournier, SA | |
| | 33 | CA 2,372,576 | 02-10-2004 | Laboratoires Fournier, SA | |

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|-----------------------|--|--------------------|--|
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